



Mini Summit 4: Update on Federal Government Pharmaceutical Price Negotiations

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First 10 drugs up for price negotiations

Drug Name	Therapeutic Area	Participating Manufacturer
Eliquis	Blood thinner	Bristol Myers Squibb
Jardiance	Diabetes	Boehringer Ingelheim
Xarelto	Blood thinner	Janssen Pharms
Januvia	Diabetes	Merck Sharp Dohme
Farxiga	Diabetes, heart failure, and chronic kidney disease	AstraZeneca AB
Entresto	Heart failure	Novartis Pharms Corp
Enbrel	Rheumatoid arthritis	Immunex Corporation
Imbruvica	Blood cancers	Pharmacyclics LLC
Stelara	Psoriasis and Crohn's Disease	Janssen Biotech, Inc.
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Diabetes	Novo Nordisk Inc.

CMS Timeline

Q: What are the key dates for implementation of this new program for the first cycle of negotiation?

- **August 29, 2023** – CMS published the list of 10 drugs covered under Medicare Part D selected for negotiation for 2026.
- **October 1, 2023** – Deadline for drug companies that manufacture the drugs selected for the Negotiation Program for 2026 to decide whether they will sign agreements to participate in the Negotiation Program.
- **October 2, 2023** – Deadline for drug companies that manufacture the drugs selected for the Negotiation Program for 2026 and that have signed an agreement to participate in the Negotiation Program (participating drug companies) to submit manufacturer-specific data to CMS for consideration in the negotiation of a maximum fair price. In addition, this is the deadline for the public to submit data on therapeutic alternatives to the selected drugs, data related to unmet medical need, and data on impacts to specific populations.
- **Fall 2023** – CMS will provide additional engagement opportunities through patient-focused listening sessions. These listening sessions will be open to the public, including patients, beneficiaries, caregivers, patient/consumer advocacy organizations, and other interested parties to participate. Additional information about these public listening sessions will be forthcoming.

CMS will provide an additional engagement opportunity for participating drug companies that manufacture selected drugs to meet with CMS to discuss their October 2 data submissions.
- **February 1, 2024** – Deadline for CMS to send an initial offer of a maximum fair price for a selected drug with a concise justification to each participating drug company.
- **March 2, 2024** – Deadline for participating drug companies to accept the initial offer of a maximum fair price or propose a counteroffer, if desired. Companies have 30 days from receiving CMS' initial offer to respond.
- **Spring/Summer 2024** – CMS will provide up to three negotiation meetings with participating drug companies, if a counteroffer is provided by the drug company and CMS does not accept the counteroffer.
- **August 1, 2024** – The negotiation period will end.
- **September 1, 2024** – CMS will publish the negotiated maximum fair prices for drugs selected for negotiation for 2026 for drug companies participating in the Negotiation Program.
- **March 1, 2025** – Deadline for CMS to publish the explanation of the maximum fair prices that have been negotiated for drugs selected for negotiation for 2026.
- **January 1, 2026** – Maximum fair prices negotiated for selected drugs become effective.

Key Takeaways



Identify whom at the company will have a seat at the table come negotiation time



Mind the deadlines, especially for submitting written counteroffers